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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,047	07/11/2002	Ivar Mendez	GRON-3402	6583

5409 7590 10/05/2005

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,047	MENDEZ, IVAR	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-7,15-18,21-33 and 35-37* is/are allowed.

6)☒ Claim(s) *1,8,9 and 11-14* is/are rejected.

7)☒ Claim(s) *10,19,20 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/16/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

The objection to claims 1 and 2 is withdrawn in light of the amendment dated 7/7/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,8-9,11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (USPN 4,710,180) in view of Shapiro et al (USPN 4,415,101). Johnson discloses a syringe (see figure 1) with a barrel (6) and plunger (8) and cannula (4) having a single passageway (16) with an open upper end (18), a lower end (14) defining a blunt closed tip (22) and a pair of side port holes (24). The side port holes (24) are essentially diametrically opposed yet slightly offset from being completely diametrically opposed. See figure 4 below.

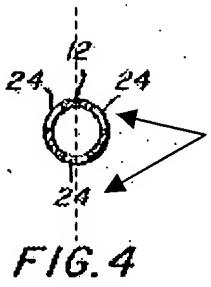

FIG. 4

Pair of side port holes (24) that are diametrically opposed in that they are positioned on opposite sides of the diameter of the cannula but are slightly offset from being truly oppositely positioned.

Regarding claims 8-9, the cannula (4) has a length that is sufficient to linearly penetrate and enter a host brain where the holes would be concurrently positionable at a predetermined

target site. See figure 1. As shown in the drawing, the cannula has an outside diameter of **about** 0.8mm.

Regarding claims 11 and 14, as shown in figure 4 the side port holes (24) have the same diameter. The cannula is made from stainless steel. See 2:44.

Johnson meets the claim limitations as described above but fails to include a microinjector for incremental depression of the plunger to result in metered delivery of the contents of the syringe barrel through the cannula port holes.

Shapiro discloses an incremental liquid dispensing device that includes a syringe barrel (13), a plunger (15) and a microinjector (11). The microinjector is attached to the proximal end of the syringe (21) and the plunger (26). The microinjector is designed to incrementally drive the plunger. See Summary and 3:20-21.

At the time of the invention, it would have been obvious to incorporate the microinjector of Shapiro into the invention of Johnson to provide a controlled mechanism for injection. Both devices are analogous in the syringe/injection art; therefore, a combination is proper. Additionally, one skilled in the art would recognize that a known problem exists in the art of manual injectors, such as the Johnson syringe. Manual injectors are subject to variations of injection pressure and volume. Furthermore, the application of Johnson may be greatly affected by fluctuations in injection pressure in that the changes of pressure may potentially alter or destroy the living cells being injected. Therefore, one skilled in the art would recognize the need for an automated incremental injector to provide a known injection volume and rate. One skilled in the art would have garnered the motivation for the incorporation in order to provide a solution to a known problem in the syringe art.

Regarding the new claim language, the syringe of Johnson and the injector of Shapiro are adapted for interconnection since Shapiro teaches the use of the injector with a syringe. Additionally, the interconnected configuration facilitates delivery of along a single trajectory in a three dimensional spiral array since the user of the combined device can while withdrawing the device from the user turn the device thereby causing a three dimensional array of the drug delivery.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (USPN 4,710,180) in view of Shapiro et al (USPN 4,415,101). Johnson in view of Shapiro meet the claim limitations as described above but fail to discloses a the side port holes having a diameter of 0.3mm and the microinjector being manufactured from acetal nylon and ionized aluminum.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to make the side port holes the diameter as claimed. Applicant has not disclosed that the claimed diameter provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Johnson in view of Shapiro and applicant's invention to perform equally well with either the diameter as shown by Johnson or the claimed diameter because either diameter would allow for the passage of a typical human cell assuming a cell diameter of about 10 microns. Therefore, it would have been obvious to modify Johnson in view of Shapiro with the claimed side port diameter because such a modification would have been a design consideration which fails to patentably distinguish over the prior art.

Further, the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to make the microinjector from the materials claimed. Applicant has not disclosed that the claimed materials provide an advantage, are used for a particular purpose or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Johnson in view of Shapiro and applicant's invention to perform equally well with either the materials of Johnson in view of Shapiro or the claimed materials because both materials would perform the same function of providing a microinjector with sufficient rigidity to depress the plunger to initiate an injection. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Therefore, it would have been obvious to modify Johnson in view of Shapiro with the claimed materials because such a modification would have been a design consideration which fails to patentably distinguish over the prior art.

Allowable Subject Matter

Claims 10, 19-20 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2-7, 15-18,21-33 and 35-37 are allowed.

Response to Arguments

In response to applicant's argument that the instant application and the prior art are used for different medical procedures, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant argues that the prior art ports are not diametrically opposed and offset. However, to be diametrically opposed and offset is relative and one may even say contradictory. However, the ports can be radially offset, longitudinally offset or laterally offset. The claim language provides no further guidance; therefore, the term offset has been interpreted in its broadest meaning. It is suggested that applicant further define in the claims how the ports are diametrically opposed and still offset, i.e. longitudinally, radially, or laterally.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams
October 1, 2005

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700